

1 10A NCAC 14C .2702 is proposed to be amended as follows:

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3 **10A NCAC 14C .2702 INFORMATION REQUIRED OF APPLICANT**

4 (a) An applicant proposing to acquire an MRI scanner, including a mobile MRI scanner, shall use the Acute Care
5 Facility/Medical Equipment application form.

6 (b) Except for proposals to acquire mobile MRI scanners that serve two or more host facilities, both the applicant
7 and the person billing the patients for the MRI service shall be named as co-applicants in the application form.

8 (c) An applicant proposing to acquire a magnetic resonance imaging scanner, including a mobile MRI scanner, shall
9 provide the following information:

- 10 (1) documentation that the proposed fixed MRI scanner, excluding fixed extremity and breast MRI
11 scanners, shall be available and staffed for use at least 66 hours per week;
- 12 (2) documentation that the proposed mobile MRI scanner shall be available and staffed for use at least
13 40 hours per week;
- 14 (3) documentation that the proposed fixed extremity or dedicated breast MRI scanner shall be
15 available and staffed for use at least 40 hours per week;
- 16 (4) the average charge to the patient, regardless of who bills the patient, for each of the 20 most
17 frequent MRI procedures to be performed for each of the first three years of operation after
18 completion of the project and a description of items included in the charge; if the professional fee
19 is included in the charge, provide the dollar amount for the professional fee;
- 20 (5) if the proposed MRI service will be provided pursuant to a service agreement, the dollar amount of
21 the service contract fee billed by the applicant to the contracting party for each of the first three
22 years of operation;
- 23 (6) letters from physicians indicating their intent to refer patients to the proposed magnetic resonance
24 imaging scanner and their estimate of the number of patients proposed to be referred per year,
25 which is based on the physicians' historical number of referrals;
- 26 (7) for each location in the MRI service area at which the applicant or a related entity will provide
27 MRI services, utilizing existing, approved, or proposed fixed MRI scanners, the number of fixed
28 MRI scanners operated or to be operated at each location;
- 29 ~~(7)~~ (8) for each location in the MRI service area at which the applicant or a related entity will provide
30 MRI services, utilizing existing, approved, or proposed fixed MRI scanners, projections of the
31 annual number of unweighted MRI procedures to be performed for each of the four types of MRI
32 procedures, as identified in the SMFP, for each of the first three years of operation after
33 completion of the project;
- 34 ~~(8)~~ (9) for each location in the MRI service area at which the applicant or a related entity will provide
35 services, utilizing existing, approved, or proposed fixed MRI scanners, projections of the annual
36 number of weighted MRI procedures to be performed for each of the four types of MRI

- 1 procedures, as identified in the SMFP, for each of the first three years of operation after
2 completion of the project;
- 3 ~~(9)~~ (10) a detailed description of the methodology and assumptions used to project the number of
4 unweighted MRI procedures to be performed at each location, including the number of contrast
5 versus non-contrast procedures, sedation versus non-sedation procedures, and inpatient versus
6 outpatient procedures;
- 7 ~~(10)~~ (11) a detailed description of the methodology and assumptions used to project the number of
8 weighted MRI procedures to be performed at each location;
- 9 ~~(11)~~ (12) for each ~~existing fixed or existing, approved or proposed~~ mobile MRI scanner owned by the
10 applicant or a related entity and operated in North Carolina in the month the application is
11 submitted, the vendor, tesla strength, serial number or vehicle identification number, CON project
12 identification number, ~~physical location for fixed MRI scanners, and host sites for mobile MRI~~
13 ~~scanners; sites;~~
- 14 ~~(12)~~ (13) ~~for each approved fixed or mobile MRI scanner to be owned by the applicant or a related entity~~
15 ~~and approved to be operated in North Carolina, the proposed vendor, proposed tesla strength, CON~~
16 ~~project identification number, physical location for fixed MRI scanners, and host sites for mobile~~
17 ~~MRI scanners; for each host site in the mobile MRI region in which the applicant or a related entity~~
18 ~~will provide the proposed mobile MRI services, utilizing existing, approved, or proposed mobile~~
19 ~~MRI scanners, projections of the annual number of unweighted and weighted MRI procedures to~~
20 ~~be performed for each of the four types of MRI procedures, as identified in the SMFP, for each of~~
21 ~~the first three years of operation after completion of the project;~~
- 22 ~~(13)~~ (14) if proposing to acquire a mobile MRI scanner, an explanation of the basis for selection of the
23 proposed host sites if the host sites are not located in MRI service areas that lack a fixed MRI
24 scanner; and
- 25 ~~(14)~~ (15) identity of the accreditation authority the applicant proposes to use.
- 26 (d) An applicant proposing to acquire a mobile MRI scanner shall provide copies of letters of intent from, and
27 proposed contracts with, all of the proposed host facilities of the new MRI scanner.
- 28 (e) An applicant proposing to acquire a dedicated fixed breast MRI scanner shall demonstrate that:
- 29 (1) it has an existing and ongoing working relationship with a breast-imaging radiologist or radiology
30 practice group that has experience interpreting breast images provided by mammography,
31 ultrasound, and MRI scanner equipment, and that is trained to interpret images produced by a MRI
32 scanner configured exclusively for mammographic studies;
- 33 (2) for the last 12 months it has performed the following services, without interruption in the provision
34 of these services: breast MRI procedures on a fixed MRI scanner with a breast coil, mammograms,
35 breast ultrasound procedures, breast needle core biopsies, breast cyst aspirations, and pre-surgical
36 breast needle localizations;

- 1 (3) its existing mammography equipment, breast ultrasound equipment, and the proposed dedicated
2 breast MRI scanner is in compliance with the federal Mammography Quality Standards Act;
- 3 (4) it is part of an existing healthcare system that provides comprehensive cancer care, including
4 radiation oncology, medical oncology, surgical oncology and an established breast cancer
5 treatment program that is based in the geographic area proposed to be served by the applicant; and,
- 6 (5) it has an existing relationship with an established collaborative team for the treatment of breast
7 cancer that includes, radiologists, pathologists, radiation oncologists, hematologists/oncologists,
8 surgeons, obstetricians/gynecologists, and primary care providers.
- 9 (f) An applicant proposing to acquire an extremity MRI scanner, pursuant to a need determination in the State
10 Medical Facilities Plan for a demonstration project, shall:
- 11 (1) provide a detailed description of the scope of the research studies that shall be conducted to
12 demonstrate the convenience, cost effectiveness and improved access resulting from utilization of
13 extremity MRI scanning;
- 14 (2) provide projections of estimated cost savings from utilization of an extremity MRI scanner based
15 on comparison of "total dollars received per procedure" performed on the proposed scanner in
16 comparison to "total dollars received per procedure" performed on whole body scanners;
- 17 (3) provide projections of estimated cost savings to the patient from utilization of an extremity MRI
18 scanner;
- 19 (4) commit to prepare an annual report at the end of each of the first three operating years, to be
20 submitted to the Medical Facilities Planning Section and the Certificate of Need Section, that shall
21 include:
- 22 (A) a detailed description of the research studies completed;
- 23 (B) a description of the results of the studies;
- 24 (C) the cost per procedure to the patient and billing entity;
- 25 (D) the cost savings to the patient attributed to utilization of an extremity MRI scanner;
- 26 (E) an analysis of "total dollars received per procedure" performed on the extremity MRI
27 scanner in comparison to "total dollars received per procedure" performed on whole body
28 scanners; and
- 29 (F) the annual volume of unweighted and weighted MRI procedures performed, by CPT
30 code;
- 31 (5) identify the operating hours of the proposed scanner;
- 32 (6) provide a description of the capabilities of the proposed scanner;
- 33 (7) provide documentation of the capacity of the proposed scanner based on the number of days to be
34 operated each week, the number of days to be operated each year, the number of hours to be
35 operated each day, and the average number of unweighted MRI procedures the scanner is capable
36 of performing each hour;

- (8) identify the types of MRI procedures by CPT code that are appropriate to be performed on an extremity MRI scanner as opposed to a whole body MRI scanner;
- (9) provide copies of the operational and safety requirements set by the manufacturer; and
- (10) describe the criteria and methodology to be implemented for utilization review to ensure the medical necessity of the procedures performed.

(g) An applicant proposing to acquire a multi-position MRI scanner, pursuant to a need determination in the State Medical Facilities Plan for a demonstration project, shall:

- (1) commit to prepare an annual report at the end of each of the first three operating years, to be submitted to the Medical Facilities Planning Section and the Certificate of Need Section, that shall include:
 - (A) the number of exams by CPT code performed on the multi-position MRI scanner in an upright or nonstandard position;
 - (B) the total number of examinations by CPT code performed on the multi-position MRI scanner in any position;
 - (C) the number of doctors by specialty that referred patients for an MRI scan in an upright or nonstandard position;
 - (D) documentation to demonstrate compliance with the Basic Principles policy included in the State Medical Facilities Plan;
 - (E) a detailed description of the unique information that was acquired only by use of the multi-position capability of the multi-position MRI scanner; and
 - (F) the number of insured, underinsured, and uninsured patients served by type of payment category;
- (2) provide the specific criteria that will be used to determine which patients will be examined in other than routine supine or prone imaging positions;
- (3) project the number of exams by CPT code performed on the multi-position MRI scanner in an upright or nonstandard position;
- (4) project the total number of examinations by CPT code performed on the multi-position MRI scanner in any position;
- (5) demonstrate that access to the multi-position MRI scanner will be made available to all spine surgeons in the proposed service area, regardless of ownership in the applicant's facility;
- (6) demonstrate that at least 50 percent of the patients to be served on the multi-position MRI scanner will be spine patients who are examined in an upright or nonstandard position; and
- (7) provide documentation of the capacity of the proposed fixed multi-position MRI scanner based on the number of days to be operated each week, the number of days to be operated each year, the number of hours to be operated each day, and the average number of unweighted MRI procedures the scanner is capable of performing each hour.

1 *History Note:* *Authority G.S. 131E-177(1); 131E-183(b);*
2 *Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule*
3 *becomes effective, whichever is sooner;*
4 *Eff. February 1, 1994;*
5 *Temporary Amendment Eff. January 1, 2003; January 1, 2002;*
6 *Amended Eff. August 1, 2004; April 1, 2003;*
7 *Temporary Amendment Eff. January 1, 2005;*
8 *Amended Eff. November 1, 2005;*
9 *Temporary Amendment Eff. February 1, 2006;*
10 *Amended Eff. November 1, 2006;*
11 *Temporary Amendment Eff. February 1, 2008.*